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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,291	06/10/2005	Kazufumi Yazaki	Q88235	9414

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SUGHRUE MION, PLLC  
2100 PENNSYLVANIA AVENUE, N.W.  
SUITE 800  
WASHINGTON, DC 20037

EXAMINER
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MEAH, MOHAMMAD Y

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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01/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/538,291	<b>Applicant(s)</b> KAZUFUMI	
	<b>Examiner</b> Mohammad Meah	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,6,7,10-13 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,7,10-13 and 16-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/11/07 has been entered.

Claims 1-4, 6-7, 10-13 and 16-19 are pending. Claims 1-3 and 17-19 remain withdrawn. Claims 4, 6-16 were examined in the previous action. With supplemental amendment of this application, the applicant, on dates on 10/11/07, cancelled claim 8-9, 14-15 and amended claims 1-4, 6-7 and 17-19.

### ***Claim Rejections***

#### ***I. 35 U.S.C 112 2<sup>nd</sup> paragraph***

Rejection of claims 4, 6-7, 10-13 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, is withdrawn after applicants argument and amendments.

#### ***II. USC 112 rejection 1<sup>st</sup> paragraph written description***

Rejection of Claims 4, 6-7, 10-13 under 35 U.S.C. 112, first paragraph written description, is withdrawn after applicants argument and amendments.

*III. USC 112 rejection 1<sup>st</sup> paragraph Enablement requirement*

Rejection of Claims 4, 6-7, 10-13 under 35 U.S.C. 112, first paragraph Enablement requirement, is withdrawn after applicants argument and amendments.

*IV. 35 U.S.C 103a Rejection*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 6-7, 10-13 are rejected under 35 U.S.C. 103(a) Rowbury et al. ( J. appld. Microbiol. 2001, 90, 677-695) in view of Lockwood et al (WO 94/19472, in IDS) and Seaver et al. ( J. Bacterol. 2001. pp 7182-7189).

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Claims 4, 6-7, 10-13 are directed to *E. coli* strain expressing any exogenous gene encoding PAL protein, wherein said strain is selected by measuring hydrogen decomposition as a stress response factor.

Lockwood et al (WO 94/19472, in IDS) teach expression of genes encoding unstable proteins, such as the Pal protein in *E. coli* strain. However Lockwood et al is silent about a correlation between stress response and high an expression of exogenous gene in *E. coli*.

Rowbury et al. ( J. appld Microbiol 2001, 90, 677-695) teach that in cells of microorganisms, such as *E. coli* the stress response increases upon expression of exogenous material including genes (such as a foreign biological component, bacteriophages etc, page 678 and Table 1). Rowbury et al. also teach that such stress can be correlated with hydrogen peroxide build-up inside the cell ( page 692 last paragraph).

Seaver et al. teach measurement of hydrogen peroxide decomposition activity in growing *E. coli* strain. Seaver also teach that hydrogen peroxide forms in *E. coli* strain when said strain shows stress. It is easier to monitor stress response in *E. coli* by measuring the hydrogen peroxide decomposition.

Therefore a person of ordinary skill in the art is **motivated** to use Seaver's method of measuring hydrogen peroxide decomposition activity to select *E. coli* strain expressing PAL gene ( as taught by Lockwood et al) wherein increase of exogenous gene is correlated with increase in stress response of said *E. coli* strain as taught by Rowbury et al.

As such it would have been obvious to one of ordinary skill in the art to express an *E. coli* strain with an exogenous PAL gene ( as taught by Lockwood et al) and use the Seaver's method of measuring hydrogen peroxide decomposition activity to select said *E. coli* strain based on stress response. Therefore claims 4, 6-7, 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowbury et al. ( J. appld. Microbiol. 2001, 90, 677-695) in view of Lockwood et al (WO 94/19472, in IDS) and Seaver et al. ( J. Bacterol. 2001. pp 7182-7189).

Applicants argument against Rowbury et al. for not teaching stress response in *E. coli* strain is not found persuasive. In fact whole review article is on stressed *E. coli* strain. Rowbury et al. teach that in *E. coli* the stress response increases upon introducing a foreign biological component ( such as bacteriophages, etc, page 678 and Table 1) bacteriophages comprise an exogenous gene. Applicants argument that Seaver et al. ( J. Bacterol. 2001. pp 7182-7189) do not teach measurement of hydrogen peroxide decomposition activity in growing *E. coli* as a means of stress response factor is not found to be true as Seaver et al. in the Discussion section of the article ( page 7187 ) discussed quantification of hydrogen peroxide decomposition as a means of stress in growing *E. coli*.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohammad Younus Meah, PhD

A handwritten signature in black ink, appearing to read 'Meah', is positioned below the typed name.

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Examiner, Art Unit 1652

Recombinant Enzymes, 3C31 Remsen Bld

400 Dulany Street, Alexandria, VA 22314

Telephone: 517-272-1261